

A Phase 2 Study to Evaluate the Efficacy and Safety of ENN0403 in Subjects with DME

NCT06708260

Status	RECRUITING
Phase	Phase 2
Sponsor	EnnovaBio
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (5)

- Provide written informed consent;
- Aware of the entire study process and requirements, understands the importance of medication compliance and completing all assessments on time throughout the study, and agrees to strictly follow the protocol and study procedures, including restrictions on drug combination during the study;
- Diagnosis of type 1 or type 2 diabetes mellitus and HbA1c \leq 10.0% with regular use hypoglycemic drugs and stable glycemic control 1 month before screening (at the discretion of the investigator);
- The decrease of BCVA is mainly caused by Diabetic Macular Edema in the study eye;
- Optical Coherence Tomography (OCT) foveal CRT at screening measuring $\leq 300\mu$.

Exclusion (10)

- Study eye with any eye disease or medical history other than DME that causes or may cause irreversible vision loss;
 - Study eye had glaucoma filtration surgery in the past or may have the surgery during the study;
 - Study eye had previously undergone vitreoretinal surgery;
 - Study eye received intraocular hormone drugs within 6 months prior to baseline or periocular or systemic hormone drugs within 3 months prior to baseline;
 - Any eye received intraocular injection of VEGF within 3 months prior to baseline;
- ... and 5 more (see full listing online)

Locations (1 total)

Tianjin Medical University Eye Hospital, Tianjin, Tianjin Municipality, China